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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.        |
|--|-------------|----------------------|-------------------------|-------------------------|
| 10/562,762   | 12/27/2005  | Massimo Ferrari      | 207,385                 | 8763                    |
| 7590   | 03/17/2008  |                      |                         |                         |
| Jay S Cinamon<br>Abelman Frayne & Schwab<br>10th Floor<br>666 Third Avenue<br>New York, NY 10017 |             |                      |                         | EXAMINER<br>MABRY, JOHN |
|  |             |                      | ART UNIT<br>1625        | PAPER NUMBER            |
|  |             |                      | MAIL DATE<br>03/17/2008 | DELIVERY MODE<br>PAPER  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/562,762             | FERRARI ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | John Mabry, PhD        | 1625                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 January 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 26-45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

***Examiner's Response***

Applicant's response on January 4, 2008 filed in response to the Office Action dated September 4, 2007 has been received and duly noted. In view of this response, the status of the rejection/objections of record are as follows:

***Objection***

Applicant's argument that missing and cutoff pages of the Specification is withdrawn. The Examiner acknowledges the inclusion of complete pages that were incomplete in Specification at the time of examination. Applicant has remedied this problem by submission of these page to overcome this objection.

***35 USC § 112***

The 112-2<sup>nd</sup> rejection regarding claims 26-45 stands and have not been overcome. Applicant has failed to completely amend the claims to overcome this rejection. For example, the term "possibly" still remains in claim 40 (see amended claim set).

The 112-2<sup>nd</sup> rejection regarding claims 26-45 regarding the terms "D(0.9)", "D(0.5)" and "D[4.3]" have been overcome in view of Applicant's argument.

The 112-2<sup>nd</sup> rejection regarding claims 26-45 stands and have not been overcome. Applicant has failed to completely amend the claims to overcome this

rejection. For example, the phrase “in the presence or tributylamine” remains in claim 28.

The 112-2<sup>nd</sup> rejection regarding claims 26-45 stands and have not been overcome. Applicant has failed to completely amend the claims to overcome this rejection. The original structure (VI) needs to be struck-through in its entirety, not simply the “OCOCH3-” portion. This is in part due to Applicant adding a new structure (VI).

***35 USC § 103(a)***

The 103(a) of record regarding claims 26-45 stands and have not been overcome.

On bottom of page 9 and top of page 10 in Applicant’s Remarks, Applicant argues that (EP62503) Jones 2 uses methane sulphonic acid in the deprotection of Formula (VI) to make Formula (I). Applicant is arguing away from Examiner’s rejection as described in Office Action. Applicant is arguing the details of (EP62503) Jones 2 and its disadvantages compared to instant application. However, in the Non-Final Office action, the Examiner clearly describes US 4,358,593 (Jones 1). Jones 1 clearly describes the deprotection of acetoxy compound of Formula (VI) with treatment of sodium hydroxide in methanol, followed by acidification to pH 2-3 (which is in alignment with claimed invention) then readjusted to basic pH 8 which results in the non-salt raloxifene (I) (see Example 14, column 14). Jones 1 does not teach the raloxifene HCl salt (I) as the final product; however, Jones 2 also teaches that deprotection can take place readily with sodium hydroxide in an alcoholic solution followed by acid catalysts,

more specifically HCl, to obtain raloxifene HCl salt (I) (see column 7, lines 17-68 and column 8, lines 1-37). The claimed invention reads on the teachings as disclosed by Jones 1.

Examiner's original argument in Non-Final Office Action clearly describes how the instant application is unpatentable over Jones et al (US 4,358,593) in view of Jones et al (EP62503) and in further view of Alt (US 5,523,416). The Examiner believes that an artisan of ordinary skill would be motivated to use said references (along with judicious selection and routine optimization) and achieve the instant invention.

The adjustment of particular conventional working conditions (e.g. determining result effective amounts of the ingredients beneficially taught by the cited references), as well as adjustment of reaction temperature, reaction time and use of solvents, interchanging a particular acid and/or base, not isolating intermediates, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan (*In re Mostovych, Weber, Mitchell and Aulbach*, 144 USPQ 38). Accordingly, these types of modifications would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry, PhD/  
Examiner  
Art Unit 1625

/Rita J. Desai/  
Primary Examiner, Art Unit 1625